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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/451,527	12/01/99	SIM G	IM-2-C2

026949
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HM12/0313

EXAMINER	
KAUSHAL,S	
ART UNIT	**PAPER NUMBER**
1633	6

DATE MAILED: 03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/451,527	Applicant(s) SIM ET AL.	
	Examiner Sumesh Kaushal	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Polynucleotides

1. Claims 1-17, 23-29, and 30-31, drawn to isolated nucleic acid molecules, method of making recombinant protein and therapeutic composition (**Canine IL-4**), classified in class 536, subclass 23.1.

2. Claims 1-17, 23-29, and 30-31, drawn to isolated nucleic acid molecules, method of making recombinant protein and therapeutic composition (**Canine Flt-3L**), classified in class 536, subclass 23.1.

3. Claims 1-17, 23-29, and 30-31, drawn to isolated nucleic acid molecules, method of making recombinant protein and therapeutic composition (**Feline Flt-3L**), classified in class 536, subclass 23.1.

4. Claims 1-17, 23-29, and 30-31, drawn to isolated nucleic acid molecules, method of making recombinant protein and therapeutic composition (**Canine CD40**), classified in class 536, subclass 23.1.

5. Claims 1-17, 23-29, and 30-31, drawn to isolated nucleic acid molecules, method of making recombinant protein and therapeutic composition (**Feline CD40**), classified in class 536, subclass 23.1.

6. Claims 1-17, 23-29, and 30-31, drawn to isolated nucleic acid molecules, method of making recombinant protein and therapeutic composition (**Canine CD154**), classified in class 536, subclass 23.1.

7. Claims 1-17, 23-29, and 30-31, drawn to isolated nucleic acid molecules, method of making recombinant protein and therapeutic composition (**Feline CD154**), classified in class 536, subclass 23.1.

8. Claims 1-17, 23-29, and 30-31, drawn to isolated nucleic acid molecules, method of making recombinant protein and therapeutic composition (**Canine IL-5**), classified in class 536, subclass 23.1.

9. Claims 1-17, 23-29, and 30-31, drawn to isolated nucleic acid molecules, method of making recombinant protein and therapeutic composition (**Canine IL-13**), classified in class 536, subclass 23.1.

10. Claims 1-17, 23-29, and 30-31, drawn to isolated nucleic acid molecules, method of making recombinant protein and therapeutic composition (**Feline IFN-alpha**), classified in class 536, subclass 23.1.

11. Claims 1-17, 23-29, and 30-31, drawn to isolated nucleic acid molecules, method of making recombinant protein and therapeutic composition (**Feline GMCSF**), classified in class 536, subclass 23.1.

Proteins

12. Claims 18-19, 23-24 and 26-28 drawn to isolated protein and therapeutic composition (**Canine IL-4**), classified in class 530, subclass 350.

13. Claims 18-19, 23-24 and 26-28 drawn to isolated protein and therapeutic composition (**Canine Flt-3L**), classified in class 530, subclass 350.

14. Claims 18-19, 23-24 and 26-28 drawn to isolated protein and therapeutic composition (**Feline Flt-3L**), classified in class 530, subclass 350.

15. Claims 18-19, 23-24 and 26-28 drawn to isolated protein and therapeutic composition (**Canine CD40**), classified in class 530, subclass 350.

16. Claims 18-19, 23-24 and 26-28 drawn to isolated protein and therapeutic composition (**Feline CD40**), classified in class 530, subclass 350.

17. Claims 18-19, 23-24 and 26-28 drawn to isolated protein and therapeutic composition (**Canine CD154**), classified in class 530, subclass 350.

18. Claims 18-19, 23-24 and 26-28 drawn to isolated protein and therapeutic composition (**Feline CD154**), classified in class 530, subclass 350.

19. Claims 18-19, 23-24 and 26-28 drawn to isolated protein and therapeutic composition (**Canine IL-5**), classified in class 530, subclass 350.

20. Claims 18-19, 23-24 and 26-28 drawn to isolated protein and therapeutic composition (**Canine IL-13**), classified in class 530, subclass 350.

21. Claims 18-19, 23-24 and 26-28 drawn to isolated protein and therapeutic composition (**Feline IFN-alpha**), classified in class 530, subclass 350.

22. Claims 18-19, 23-24 and 26-28 drawn to isolated protein and therapeutic composition (**Feline GMCSF**), classified in class 530, subclass 350.

Antibodies

23. Claims 20, 22-24 and 26-28, drawn to isolated antibodies and therapeutic composition (**Canine IL-4**), classified in class 530, subclass 387.1.

24. Claims 20, 22-24 and 26-28, drawn to isolated antibodies and therapeutic composition (**Canine Flt-3L**), classified in class 530, subclass 387.1.

25. Claims 20, 22-24 and 26-28, drawn to isolated antibodies and therapeutic composition (**Feline Flt-3L**), classified in class 530, subclass 387.1.

26. Claims 20, 22-24 and 26-28, drawn to isolated antibodies and therapeutic composition (**Canine CD40**), classified in class 530, subclass 387.1.

27. Claims 20, 22-24 and 26-28, drawn to isolated antibodies and therapeutic composition (**Feline CD40**), classified in class 530, subclass 387.1.

28. Claims 20, 22-24 and 26-28, drawn to isolated antibodies and therapeutic composition (**Canine CD154**), classified in class 530, subclass 387.1.

29. Claims 20, 22-24 and 26-28, drawn to isolated antibodies and therapeutic composition (**Feline CD154**), classified in class 530, subclass 387.1.

30. Claims 20, 22-24 and 26-28, drawn to isolated antibodies and therapeutic composition **Canine IL-5**), classified in class 530, subclass 387.1.

31. Claims 20, 22-24 and 26-28, drawn to isolated antibodies and therapeutic composition (**Canine IL-13**), classified in class 530, subclass 387.1.

32. Claims 20, 22-24 and 26-28, drawn to isolated antibodies and therapeutic composition (**Feline IFN-alpha**), classified in class 530, subclass 387.1.

33. Claims 20, 22-24 and 26-28, drawn to isolated antibodies and therapeutic composition (**Feline GMCSF**), classified in class 530, subclass 387.1.

Mimetopes

34. Claims 23-24 and 26-28, drawn to mimetope, therapeutic compositions and method to regulate immune response (**Canine IL-4**), classified in class 424, subclass 9.1.

35. Claims 23-24 and 26-28, drawn to mimetope, therapeutic compositions and method to regulate immune response (**Canine Flt-3L**), classified in class 424, subclass 9.1.

36. Claims 23-24 and 26-28, drawn to mimetope, therapeutic compositions and method to regulate immune response (**Feline Flt-3L**), classified in class 424, subclass 9.1.

37. Claims 23-24 and 26-28, drawn to mimetope, therapeutic compositions and method to regulate immune response (**Canine CD40**), classified in class 424, subclass 9.1.

38. Claims 23-24 and 26-28, drawn to mimetope, therapeutic compositions and method to regulate immune response (**Feline CD40**), classified in class 424, subclass 9.1.

39. Claims 23-24 and 26-28, drawn to mimetope, therapeutic compositions and method to regulate immune response (**Canine CD154**), classified in class 424, subclass 9.1.

40. Claims 23-24 and 26-28, drawn to mimetope, therapeutic compositions and method to regulate immune response (**Feline CD154**), classified in class 424, subclass 9.1.

41. Claims 23-24 and 26-28, drawn to mimetope, therapeutic compositions and method to regulate immune response (**Canine IL-5**), classified in class 424, subclass 9.1.

42. Claims 23-24 and 26-28, drawn to mimetope, therapeutic compositions and method to regulate immune response (**Canine IL-13**), classified in class 424, subclass 9.1.

43. Claims 23-24 and 26-28, drawn to mimetope, therapeutic compositions and method to regulate immune response(**Feline IFN-alpha**), classified in class 424, subclass 9.1.

44. Claims 23-24 and 26-28, drawn to mimetope, therapeutic compositions and method to regulate immune response (**Feline GMCSF**), classified in class 424, subclass 9.1.

Mehtod to identify compounds

45. Claim 30, drawn to a method of identify a compound that regulates the immune response in an animal by interacting with (**Canine IL-4**), classified in class 435, subclass 375.

46. Claim 30, drawn to a method of identify a compound that regulates the immune response in an animal by interacting with (**Canine Flt-3L**), classified in class 435, subclass 375.

47. Claim 30, drawn to a method of identify a compound that regulates the immune response in an animal by interacting with (**Feline Flt-3L**), classified in class 435, subclass 375.

48. Claim 30, drawn to a method of identify a compound that regulates the immune response in an animal by interacting with (**Canine CD40**), classified in class 435, subclass 375.

49. Claim 30, drawn to a method of identify a compound that regulates the immune response in an animal by interacting with (**Feline CD40**), classified in class 435, subclass 375.

50. Claim 30, drawn to a method of identify a compound that regulates the immune response in an animal by interacting with (**Canine CD154**), classified in class 435, subclass 375.

51. Claim 30, drawn to a method of identify a compound that regulates the immune response in an animal by interacting with (**Feline CD154**), classified in class 435, subclass 375.

52. Claim 30, drawn to a method of identify a compound that regulates the immune response in an animal by interacting with (**Canine IL-5**), classified in class 435, subclass 375.

53. Claim 30, drawn to a method of identify a compound that regulates the immune response in an animal by interacting with (**Canine IL-13**), classified in class 435, subclass 375.

54. Claim 30, drawn to a method of identify a compound that regulates the immune response in an animal by interacting with (**Feline IFN-alpha**), classified in class 435, subclass 375.

55. Claim 30, drawn to a method of identify a compound that regulates the immune response in an animal by interacting with (**Feline GM-CSF**), classified in class 435, subclass 375

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-11 (nucleic acid) and 12-22 (proteins) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide can be isolated from cells endogenously expressing the polypeptide, rather than by recombinant means. Thus, these inventions are mutually exclusive and are of separate use.

Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Furthermore, inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case inventions of Groups 1-11, 12-22 and 23-3 are drawn to unrelated nucleic acid sequences, protein and antibodies respectively. These inventions are distinct because product as claimed can be used in a materially different process of using that product. For example, the nucleic acid sequence can be used for genetic probing, the cytokines (proteins) can be used to modulate cellular growth and antibodies can be use to label cell surfaces. Furthermore, Canine IL-4, Canine Flt-3L, Feline Flt-3L, Canine CD40, Feline CD40, Canine CD154 Feline CD154, Canine IL-5, Canine IL-13, Feline IFN-alpha and Feline GMCSF are structurally and functionally distinct products. Therefore inventions related to these compounds are distinct and are of separate uses.

Furthermore, inventions of Group 34-44 are distinct from inventions of Group 45-55. The therapeutic compositions and method of regulating the immune using the same require modulation of the immune response using protein mimetopes, while the methods of identifying compounds are drawn to screening compounds that binds to the cytokine as claimed. Thus these inventions are distinct and are of separate uses.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Deborah Clark can be reached on (703) 305-4051. The fax-phone number for the organization where this application or proceeding is assigned as (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Tracey Johnson, whose telephone number is (703) 308-0377. If the claims are amended canceled and/or added the applicants are advised to follow Amendment Practice under 37 CFR § 1.121 *(http://www.uspto.gov).*

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